

K073342



MAR 26 2008

Salvin Dental Specialties, Inc
3450 Latrobe Drive • Charlotte, NC 28211 • Phone 704-442-5400 • Fax 704-442-5424

510(k) Summary

- A 510(k) Owner Salvin Dental Specialties, Inc
3450 Latrobe Drive
Charlotte, NC 28211
- Contact Robert Salvin
CEO
Salvin Dental Specialties, Inc.
3450 Latrobe Drive
Charlotte, NC 28211
(704) 442-5400
(704) 442-5424
bobsalvin@salvin.com
- Preparation Date November 23, 2007
- B Trade Name Salvin Dental Specialties, Inc. Titanium Fixation Screw System
- Common Name Fixation Screw
- Classification Name Screw, Fixation, Bone
(21 CFR 888.3040, Product code HWC)
- C Predicate Device(s) K023260 – Osteomed Auto-Drive Screw System
K970912 – Leibinger Self-Drilling Screw
K050492 – Integra Bone Fixation System
K040860 – Integra Bone Fixation System
- D Device Description The *Salvin Dental Specialties Titanium Fixation Screw System* consists of 1.5mm and 2.0mm Titanium (Ti-6Al-4V) bone screws in lengths of 4, 6, 8, 10, 13 and 15mm.
- The 2.0mm diameter screws are “emergency” screws.
- The devices are provided non-sterile.

- E Intended Use The *Salvin Dental Specialties, Inc. Titanium Fixation Screw* is intended for use in internal fixation of small bones including the craniofacial and maxillofacial skeleton affected by trauma, or for reconstruction.
- Single patient use only.
- F Technological Characteristics As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.
- Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.
- G Non-Clinical Testing ASTM F 543-02 - Standard Specification and Test Methods for Metallic Medical Bone Screws
- H Clinical Testing Not applicable to this device
- I Conclusions Based on the 510(k) Summary and the information provided herein, we conclude that the *Salvin Dental Specialties Titanium Fixation Screw* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2008

Mr. Robert Salvin
Chief Executive Officer
Salvin Dental Specialties, Incorporated
3450 Latrobe Drive
Charlotte, North Carolina 28211

Re: K073342

Trade/Device Name: Salvin Dental Specialties Fixation Screw
Regulation Number: 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: March 13, 2008
Received: March 14, 2008

Dear Mr. Salvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Salvin Dental Specialties Fixation Screw

Indications for Use:

The device is intended for use in internal fixation of small bones including the craniofacial and maxillofacial skeleton affected by trauma, or for reconstruction.

Single patient use only

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RB Bete DDS for Dr S. Runner
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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